SYMBIOTICA
SPECIALITY INGREDIENTS SDN BHD

CERTIFICATE OF ANALYSIS

Product	:	Betamethasone 17 Valerate	***Manf. Date***	:	June 2018
Batch no.	:	BV 105/0618	***Retest Date***	:	May 2023

Description	White crystalline powder (White or almost white crystalline powder)
Solubility	Complies (Practically insoluble in water, freely soluble in acetone and in methylene chloride, soluble in ethanol (96%))
Identification	Test A : IR (Concordant with standard (EP)) Test B : HPLC (Complies (EP))
Melting point	196 ºC (About 192º C with decomposition)
Loss on drying	0.32 % w/w (NMT 0.5 % w/w)
Specific Optical Rotation (1% solution in Anhydrous Ethanol)	+80º (+77º to +83º on dried basis)
Related substances (HPLC)	Less than 0.05 % (Impurity A : NMT 0.7%) Less than 0.05 % (Impurity C : NMT 0.15%) Less than 0.05 % (Impurity E : NMT 0.3%) Less than 0.05 % (Impurity G : NMT 0.3%) Less than 0.05 %(Impurity H : NMT 0.15%) Less than 0.05 % (Impurity I : NMT 0.15%) Complies (Unspecified Impurity : NMT 0.10%) Less than 0.05 %(Total Impurities : NMT 1.5%)
Assay	By UV : 99.3 % w/w (NLT 97.0 % w/w and NMT 103.0 % w/w on dried basis)
Residual solvents	Methanol : NMT 3000 ppm Acetone : NMT 5000 ppm Methylene Chloride : NMT 600 ppm Ethyl Acetate : NMT 5000 ppm Complies as per ICH guidelines
Particle Size (By Laser Diffraction)	90 % ≤ 4.96 µm (Limit : 90 % ≤ 20 µm)

Conclusion : Complies with EP 9

Analytical Chemist ***QC Manager***